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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/597,738 | 06/19/2000 | H. William Bosch | 029318/0615 | 3886 |

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| EXAMINER | |
|---|---|
| HAGHIGHATIAN, MINA | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1616 | 22 |

DATE MAILED: 12/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. 09/597,738 | Applicant(s) BOSCH ET AL. | |
|---|---|---|---|
| | Examiner Mina Haghighatian | Art Unit 1616 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on *23 September 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *51-57,59-64,79-81 and 120-131* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *51-57,59-64,79-81 and 120-131* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

## DETAILED ACTION

The amendments and the Request for Reconsideration filed 09/23/2003 were entered. Claims 51-57, 59-64, 79-81 and 120-131 are pending.

### *Claim Rejections - 35 USC § 103*

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim 51-57, 59-64, 79-81 and 120-131 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wood et al (6,264,922 B1) in view of Saidi et al (6,241,969 B1).

Wood et al teach an aerosol comprising droplets of an aqueous dispersion of nanoparticles, said nanoparticles comprising insoluble therapeutic or diagnostic agent particles having a surface modifier on the surface thereof. There is also disclosed a method of making the aerosol and methods of treatment and diagnosis using the aerosol (see abstract). The droplets in the aerosols typically have a size less than about 50 microns in diameter although droplets of a much smaller size are possible. The aerosols are made by nebulizing the nanoparticle containing solution using a variety of known nebulizing techniques (col. 2, line 52 to col. 3, line 7).

Wood discloses that the therapeutic agent must be poorly soluble, which means a solubility in the liquid dispersion medium of less than about 10 mg/ml, and preferably of less than about 1 mg/ml. The preferred liquid dispersion medium is water (col. 3, lines 29-44). Suitable classes of therapeutic or diagnostic agents are disclosed in column 3,

lines 45-65, which include anti-inflammatory agents and corticosteroids. Suitable surface modifiers are disclosed in column 4, line 44 to end of column 6.

Wood also discloses that by "an effective average particle size of less than about 1000 nm" is meant that at least 90% of the particles have a weight average particle size of less than about 1000 nm when measured. More preferred is an effective average particle size of less than about 400 nm, or less than about 300 nm. In some embodiments an effective average particle size of less than about 100 nm is more preferred (col. 11, lines 47-62). Wood does not disclose species of corticosteroids and anti-inflammatory agents.

Saidi provides compositions containing corticosteroid compounds as active agents for the treatment of ailments and diseases of respiratory tract, particularly the lungs, by way of nasal and pulmonary administration. Saidi discloses the corticosteroids to include budesonide and triamcinolone acetonide (col. 3, lines 48-63). .

Saidi discloses the suitable concentration range of the corticosteroid compound in a formulation for inhalation to be in an amount from 5 $\mu$g/ml to about 5 mg/ml (col. 6, lines 31-39).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made, given the general formulations of Wood et al of aerosol formulations containing nanoparticulate drug particles, including corticosteroids, to have looked in the art for specific species of corticosteroids such as budesonide and

triamcinolone, as taught by Saidi, with the reasonable expectations of preparing an effective and specific formulation for a specific treatment.

***Double Patenting***

Claims 51-57, 59-64, 79-81 and 120-131 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of copending Application No. 09,190,138, for the reasons set forth in the Office Action mailed 10/02/02.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

***Response to Arguments***

Applicant's arguments filed 09/23/03 have been fully considered but they are not persuasive.

The amendments filed on 09/23/03 necessitated a new rejection. Thus only arguments regarding Wood et al reference (US 6,264,922) will be discussed here.

Applicant argues that Wood does not teach or suggest Applicant's claimed short administration period. However, although Wood is silent regarding the delivery time, this is considered an inherent property of a composition with similar components and limitations. Also regarding claims 51-57 and 59-64, this argument is not commensurate with the scope of the claims. It should be noted that the said instant claims recite "suitable for" which is not considered a positive recitation and is not given weight in the

examination of the claims. Furthermore the recitation of delivery time is in the preamble of the claim rather than the body of the claim.

Applicant argues that Wood does not teach or suggest the compounds required by the claims. Although this is correct, it is noted that Wood et al disclose the class of the corticosteroids and anti-inflammatory agents and the secondary prior art of record, namely, Saidi et al (6,241,969) extensively teaches the species such as triamcinolone and budesonide.

Applicant's remarks regarding the Double Patenting rejection were considered, and this rejection is held in abeyance for now.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mina Haghighatian whose telephone number is 703-308-6330. The examiner can normally be reached on core office hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 703-308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0198.

Mina Haghighatian
November 25, 2003

MICHAEL G. HARTLEY
PRIMARY EXAMINER